hidalgo

K061993

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510(k) Summary

Submitter

NOV - 3 2006

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United Kingdom

Contact: J.Pisani – Operations Director
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Manufacturer

Hidalgo Ltd
Stable Block at the Grange
20 Market St
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United Kingdom

Hidalgo propose to register as the manufacturer of the device in accordance with 21CFR Part 807.

Name of Device

Device Trade Name: Equivital™ Vital Signs Physiological Monitor

Device Common Name: Ambulatory Patient Monitor

Device Classification and Product Code:

74 DRT	870.2300 –	Monitor, Cardiac (incl Cardiotachometer & rate alarm)
74DPS	870.2340 –	Electrocardiograph
73BZQ	868.2375 -	Monitor, Breathing Frequency
80FLL	880.2910 -	Thermometer, Electronic, Clinical

Predicate Devices

The device has been compared to the following predicates:

GMP Wireless Medicine	LifeSync™	- K030795
Dymedix Inc	Re-usable Respiratory Effort Belt Sensor	- K040605
Nexan Inc	NX-300	- K003520
Protocol Systems	Propaq Encore 200	- K012451
Respironics	Actiheart®	- K052489
Vivometrics	Life Shirt™ Real Time	-K043604

Device Description

The Equivital™ Vital Signs Physiological Monitor comprises two components:

i) A chest belt containing skin electrodes and an expansion sensor

ii) A battery powered electronics module which connects directly to the chest belt and which acts to record, digitise and transmit the physiological information wirelessly to a receiving display device.

The device offers continuous monitoring of two views of the user's heart electrical activity (ECG) and respiratory breathing frequency inferred from thoracic cavity movement and uses this data to derive a Heart Rate and a Breathing Effort Rate.

The sensor also provides the following information:

- ECG and Respiration physiological waveforms.
- an indication of the user's activity level (none, low or high) derived from a movement detection sensor.
- Body orientation.
- Chest skin surface temperature.
- alternate secondary measurement of heart rate based on the detection of the user's R wave using a separate hardware processing function.
- indications and alerts if physiology exceeds predefined boundaries.

The device offers two variants for the wireless interface: a low power radio interface designed for military applications and a general purpose interface using Bluetooth™ technology.

The device offers two battery power options for the user, rechargeable or primary disposable cells.

The wireless data provided by the sensor may be viewed using a standalone PC based viewing application, or integrated into third party monitoring applications.

Intended Use Summary

The Equivital™ Vital Signs Physiological Monitor is an ambulatory multiparameter vital signs telemetry device intended for monitoring of adults (16 - 65years) in hospital care facilities, the home, workplace, and alternate care settings.

The device consists of a chest belt harness and a body worn electronics module (SEM) supported by the chest belt).

The device collects and transmits ECG data and rate, respiration data and rate, skin temperature, body orientation and motion.

The monitor is indicated for use as a general patient monitor, to provide physiological information as part of an occupational welfare monitoring system, and for general research and performance measurement purposes.

Technological Characteristics

Substantial equivalence has been measured by the technological review and comparison of performance data for the following.

The device technological characteristics compare to the following predicates:

Function	Predicate 1	Additional Predicates
ECG Heart Rate, Breathing Rate Temperature and General Physical Properties	Protocol Systems Propaq Encore 200 K003520	Nexan Inc NX-300 K003520
Chest Expansion Respiration	Dymedix Re-usable Respiratory Effort Belt – K040605	Nexan Inc NX-300 K003520 Vivometrics LifeShirt Real Time K043604
Activity/Motion Detection	Respironics Actiheart – K052489	Vivometrics LifeShirt Real Time K043604
Bluetooth telemetry and ECG transmission	GMP Wireless Medicine – LifeSync™ K030795	
Low Power 40.68MHz PAN	Respironics Actiheart – K052489	

Performance Measurement Summary

Performance measurement and review to the applicable sections of the following standards has been undertaken and successfully demonstrated as recommended by available guidance from the agency:

- EN60601-1: Medical Electrical Equipment – Part 1 General Requirements for Safety.
- IEC60601-1-2: 2001 Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility.
- ISO 10993-1: Biological Evaluation of Medical Devices: Evaluation and Testing.
- ANSI/AAMI EC13: 2002 Cardiac Monitors, heart rate meters, and alarms. The device was not evaluated against the criteria for defibrillation and pacemaker immunity as it is not indicated for use in either of these cases.
- ASTM E1112-00 Standard Specification for intermittent determination of patient temperature.

Additional voluntary testing has been undertaken to the following:

- General functional test.
- Environmental Performance Test.

The device software has been developed using a structured software lifecycle which meets the requirements of EN60601-1-4 Programmable Systems, which also applies to ongoing maintenance of the software.

Substantial Equivalence Conclusion

This pre-market notification has demonstrated the substantial equivalence of the Equivital™ Vital Signs Physiological Monitor to the predicates identified, by comparison to the descriptive material and performance testing of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2006

Hidalgo Limited
c/o Mr. Justin Pisani
Operations Director
20 Market Street
Cambridge, CB4 5QG
United Kingdom

Re: K061993
Equivital Vital Signs Physiological Monitor
Regulation Number: 21 CFR 870 1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: September 29, 2006
Received: October 5, 2006

Dear Mr. Pisani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

hidalgo

K061993

Indications for Use

510(k) Number (if known): K061993

Device Name: Equivital™ Vital Signs Physiological Monitor

Indications For Use:

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The device consists of a chest belt harness and a body worn electronics module (SEM) supported by the chest belt.

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The monitor is indicated for use as a general patient monitor, to provide physiological information as part of an occupational welfare monitoring system, and for general research and performance measurement purposes.

Federal Law (US) restricts this device to sale by or on the order of a physician

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061993